

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. [Redacted]V
(Filed: May 30, 2008; Re-filed Redacted: June 5, 2008)

NOT TO BE PUBLISHED
PUBLIC DOCUMENT

JANE DOE/17,

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Petitioner,

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Common Variable Immunodeficiency
(CVID); Collagenous Colitis;

v.

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Varicella vaccine

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

*

Thomas P. Gallagher, Gallagher & Gallagher, Somers Point, New Jersey for petitioner.

Heather Lynn Pearlman, United States Department of Justice, Washington, DC, for respondent.

DECISION¹

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL BACKGROUND

On March 31, 2004, petitioner, Jane Doe/17, filed a Petition pursuant to the National

¹ Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. Id.

Vaccine Injury Compensation Program² (“the Act” or “the Program”) alleging that the varicella vaccines³ given on March 7, 2001 and June 4, 2001 significantly aggravated a pre-existing condition. Petition (Pet.) at 1. Petitioner contends that “exposure to the varicella vaccine caused her to experience a generalized autoimmune hypersensitivity reaction.” *Id.* at 3. On October 12, 2005, respondent filed a Report pursuant to Vaccine Rule 4 contending that compensation was inappropriate and the Petition should be dismissed. To elicit expert testimony, a Hearing was held on October 19, 2007 (hereinafter “Hearing”). Petitioner presented Dr. Brian K. Adler, M.D., F.A.C.P., as an expert witness. Respondent presented Dr. Stephen J. McGeady, M.D. as an expert witness. Petitioner, Jane Doe/17, also provided fact testimony. Petitioner and respondent filed Post-Hearing Briefs on February 29, 2008, and March 24, 2008, respectively. Petitioner filed her Reply on April 18, 2008. The case is ripe for resolution.

II. FACTUAL BACKGROUND

This case presents a number of factual issues that ultimately prove critical to the resolution of this case. Petitioner’s expert relied heavily upon the information provided by petitioner for his opinion. However, petitioner’s information is either not found in the medical records or is contradicted by those records. Ultimately, petitioner’s information provided in subsequent medical histories, her affidavit and her testimony cannot be relied upon as the undersigned determined that petitioner is not a credible witness. *See pp. 14-18, infra.*

For purposes of understanding the case and the factual issues presented, this factual recitation will include both the facts as contained in the medical records and petitioner’s alleged version.

Petitioner was born on January 16, 1954. There are no contemporaneous medical records detailing petitioner’s early medical history. Petitioner discusses three medical events that become important to this case. First, petitioner developed irritable bowel syndrome (IBS)⁴ following her pregnancy in 1978. Pet. at 2. According to petitioner, she required medical treatment and it resolved within one year. *Id.* Second, petitioner claims that she developed pneumonia following each of two oral polio vaccines given in 1960 and 1962. P Submission 3

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

³The trade name for the vaccine petitioner received is Varivax. *See* Pet. at 1.

⁴Irritable bowel syndrome is “characterized by abdominal discomfort, bloating and disturbed defecation in the absence of any identifiable physical, radiologic or laboratory abnormalities indicative of organic gastrointestinal disease.” Cash BD, Chey WD, Irritable Bowel Syndrome - an evidence-based approach to diagnosis, *Aliment Pharmacol Ther.* 2004 June 15; 19(12): 1235-45. Review. PMID: 15191504 [PubMed-indexed for MEDLINE], <http://www.ncbi.nlm.nih.gov> (last visited May 29, 2008).

(hereinafter “P Sub. at _”) at 4.⁵ Petitioner filed report cards for those years showing absences from school to support her contention of extended illnesses following her receipt of the oral polio vaccines. Id. at 16-20. Third, petitioner relates that she received Rabies vaccine prior to a “sudden onset [of] life threatening serum sickness.” Id. at 7. Petitioner testified consistently at the Hearing about these alleged occurrences.

While petitioner was able to produce school report cards from over 40 years ago, petitioner was unable to produce any documentation of the hospitalizations and treatment for her two bouts of pneumonia and her life threatening serum sickness.⁶ Petitioner’s medical histories do substantiate the occurrence of the irritable bowel syndrome, however, in a very different manner. While petitioner relates that it was a one-year limited occurrence of the IBS, transcript of Hearing (hereinafter “tr. at _”) at 62, a recorded history states that “over a couple of years her symptoms improved until they reached her baseline which has been more intermittent and mild.” P Sub. 2 at 84. Petitioner claimed that the doctor, Dr. Fishman, “misunderstood” what she told him. Tr. at 39, 64. However, petitioner submitted a disability claim to the Social Security Administration (SSA) in 2000, P Sub. 11 at 454-56, one year prior to the vaccinations in question, alleging uncontrolled diarrhea from a spastic colon. Id. at 463. Petitioner dated the condition back to 1995, which is 17 years after petitioner says the condition ended and six years prior to her varicella vaccines. Also, a biopsychosocial assessment performed on petitioner in April 2000 indicates that petitioner “claims to have what is called an atonic colon,⁷ which she claims is a form of GI disorder.” Id. at 450. As discussed infra, the discrepancy between petitioner’s testimony and the information she gave to the Social Security Administration - which was consistent with the history reported by Dr. Fishman - was extremely damaging to petitioner’s credibility as a witness, and thus extremely damaging to her vaccine claim.

Petitioner was employed at the Center for AIDS Research at the University of Pennsylvania during the time of vaccination. Tr. at 9. On March 7, 2001, petitioner received a varicella vaccination in connection with clinical research study conducted by Merck and Co. and the University of Pennsylvania School of Medicine. Pet. at 1; P Sub. 2 at 17; Tr. at 8. Petitioner was a healthy control. Pet. at 1; Tr. at 10. Petitioner testified that she had a physical exam done in February 2001 by Dr. Brady prior to the trial, which included having blood work done. Tr. at 10. Petitioner testified that her tests revealed high varicella immune titers “so disseminated disease wouldn’t be a problem.” Id. In March, prior to the administration of the first vaccination, petitioner had a blood specimen drawn and frozen. Tr. at 10. Following the

⁵ Petitioner’s records were not organized and numbered in a coherent fashion. For ease of reference and identification, the undersigned will cite to the individual numbered Submissions.

⁶ There is a reference to these events in a latter history given to Dr. Derk in 2004. P Sub. 2 at 200.

⁷ Atonic means “lacking normal tone or strength; pertaining to or characterized by atony.” Dorland’s Illustrated Medical Dictionary (30th ed. 2003) 173.

immunization, laboratory results performed on April 18, 2001 indicated normal blood counts and chemistries, the only abnormalities were a slightly elevated whole blood count, MCH (mean corpuscular hemoglobin), and granulocytes, and a slightly low lymphocyte count. P Sub. 2 at 33. There is no record of any report of an adverse reaction to the vaccine. According to a log kept for the clinical study, petitioner did not report any reaction to the first vaccine. Id. at 8. The “Comments” section indicates “Feeling good.” Id. Petitioner states that she reported “soreness and swelling at injection site.” Pet. at 1; Tr. at 16.

On June 4, 2001, petitioner received her second varicella vaccination. P Sub. 2 at 15; Pet. at 2. Petitioner states that following this injection, she reported “soreness and swelling at the injection site, in addition [she] suffered flu like symptoms 2 weeks post injection, this included severe nausea, vomiting and diarrhea.” Pet. at 2. Jane Doe/17 testified that “within a week to 10 days” following the immunization she began to experience loose stools. Tr. at 18. She stated that she was going “three or four times a day.” Id. at 19. The medical records from the clinical research study dated July 16, 2001, indicate only that “Pt. reports tenderness, redness & induration” in her left deltoid beginning three days following the immunization. P Sub. 2 at 14. The log for the study indicates that “no other symptoms reported.” Id. at 8. Under the “Comments” section of the log, there is a notation that “Retrospectively (6/03) reported loose stools beginning - 7/01.” Id. Petitioner had lab chemistries performed on July 16, 2001, which showed slightly elevated WBC’s, granulocytes and slightly decreased MCH and lymphocytes. P Sub. 2 at 254.

When asked if she saw a doctor for her problems, petitioner testified that she did not see a doctor, but relied upon over-the-counter medication. Tr. at 18-19; 70.⁸ Petitioner alleges that she told the study supervisor, Dr. Kathleen Brady, about her stomach problems and that Dr. Brady “said she had no knowledge of diarrhea having anything to do with a varicella injection.” Tr. at 23. Petitioner testified that she had face-to-face meetings with study personnel in the weeks following the vaccinations and told them about her adverse events, and they took notes. Tr. at 66. There is no notation in the record of any adverse event other than the arm soreness. See P Sub. 2 at 8.

The office notes from a June 5, 2001 visit with Dr. Corey, state that petitioner was “under a lot of stress”, taking anti-depressants, had been diagnosed with depression and anxiety, and was referred to a mental health professional. P Sub. 2 at 160. Petitioner saw chiropractor Jack A. Schulman for cervical pain four times between July 13 and July 23, 2001, and two times between September 5 and 12, 2001. Id. at 245. Her chiropractor noted that petitioner responded well to spinal manipulation, ultrasound and heat for treatment. Id. at 247. Petitioner also had a full skin examination on August 2, 2001, by Dr. Rochelle Weiss. Id. at 246. Mitral valve prolapse was

⁸ When asked about records reflecting that she saw a chiropractor on four occasions during July 2001, and a dermatologist during August, petitioner did not dispute the records and her memory seemed “refreshed.” Tr. at 70-71. Petitioner’s memory appeared at times to the undersigned to be highly selective, that is she was able to remember only when it benefited her case. This was one aspect of the credibility issue the undersigned found with petitioner.

the only condition indicated under past medical history. Id. The skin lesions being evaluated were benign, and petitioner's "systems" were deemed "unremarkable." Id.

As a study participant, petitioner was evaluated at various points post-vaccination for the research study. See Tr. at 66; see also P Sub. 2 at 4-9. Thus, reports were issued at six weeks following the first injection on March 7, 2001; week 18, which was on July 16, 2001; 24 weeks, one-year and several times in the second year of the study. Id. at 8-9. Under the "Comments" section of the log, there are no reports of petitioner experiencing bowel issues. Id. It is not until June 2003 that petitioner retrospectively reported loose stools beginning on July 1, 2001. Id. at 8.

Petitioner first began to see Victor M. Fishman, M.D. at Main Line Gastroenterology Associates P.C., on March 8, 2002 to address her complaints. P Sub. 2 at 84, 92. In a consult letter to petitioner's primary care physician Dr. Corey, dated March 11, 2008, Dr. Fishman noted that petitioner was a "48-year-old white female with a chronic history of irritable bowel syndrome." Id. at 84. Dr. Fishman further explained that petitioner first experienced symptoms "at age 24 when she had 15-20 bowel movements a day, which apparently caused the premature delivery of her child." Id. Dr. Fishman also makes mention that at that time petitioner had a barium enema that showed an atonic enlarged colon. Id. In addressing petitioner's complaints Dr. Fishman writes that petitioner's symptoms "improved until they reached her baseline which has been more intermittent and mild. However, over the past eight months her symptoms have been worsening again." Id. Dr. Fishman also noted that petitioner was taking Klonopin and Celexa for depression. Id.

Dr. Fishman's assessment was that petitioner suffered from irritable bowel syndrome and that there was a history of colon cancer in her family. P Sub. 2 at 85. A colonoscopy was performed on March 22, 2002, with pathology results positive for collagenous colitis.⁹ Id. at 75. Petitioner also had lab work done on March 29, 2002, that with the exception of a slightly elevated MCH and albumin/globulin ratio and slightly low globulin, was essentially normal. Id. at 175-76.

Dr. Fishman saw petitioner for a follow-up visit on August 14, 2002. Dr. Fishman's "sense" was that Jane Doe/17 "has both collagenous colitis and irritable bowel syndrome." P Sub. 2 at 89. After a visit on August 4, 2003, Dr. Fishman concluded that "the irritable bowel is most likely responsible for her symptomatology." Id. at 98.

Petitioner saw Dr. Derk in September 2004. In his letter to Dr. Corey, Dr. Derk states that "she has a combination history of colitis and irritable bowel syndrome which will be the harbinger for most of her symptoms." P Sub. 2 at 200. In this letter, over three years post her

⁹ Collagenous colitis is "a type of colitis of unknown etiology characterized by deposits of collagenous material beneath the epithelium of the colon, with crampy abdominal pain and marked reduction in fluid and electrolyte absorption, leading to watery diarrhea; there is no mucosal ulceration." Dorland's Illustrated Medical Dictionary (30th ed. 2003) 388.

immunizations, histories first appear of petitioner's reaction to a Rabies vaccine, a proclivity to infections and a elevated white blood count following the varicella vaccinations. Id. Petitioner is the source for the information. Id. Interestingly, Dr. Derk notes that "patient reports GI symptoms for a long period of time", but does not time their onset to the vaccinations. Id.

It was not until July 2007 that petitioner's serums which were drawn and frozen before, during and after her vaccinations in 2001 were tested for immunoglobulin levels. P Sub. 8, Ex 14 at 1. The results of the testing from the March 7, 2001 sample showed petitioner's IgG at 597 mg/dL, IgA 112 mg/dL, and IgM at 102 mg/dL. Id. The results of the testing from the June 4, 2001 sample showed petitioner's IgG at 559, IgA at 111, and IgM at 96. Id. Lastly the results from the July 6, 2001 sample show her IgG at 605, IgA at 118, and IgM at 103. Id.

Currently, Jane Doe/17 reports that her illness continues; she is on permanent Social Security disability and is unable to work. Pet. at 3.

III. DISCUSSION

A. Summary of Experts' Positions

The following is a brief overview of the experts' background and opinions.

Dr. Brian K. Adler, M.D., F.A.C.P.

Dr. Adler is board-certified in internal medicine and completed his residency at Greater Baltimore Medical Center. P Status Report, filed February 6, 2006. Dr. Adler's day-to-day practice involves treating adult medicine, autoimmune disorders and many other medical problems that fall within his general practice specialty of internal medicine. Tr. at 82. Dr. Adler, during voir dire, answered that when presented with a patient he believed had an immune deficiency he would often refer the patient to an immunologist. Id. He stated that he has **minimal** experience with Common Variable Immunodeficiency (hereinafter CVID)¹⁰ and has **never diagnosed it**. Id. Without making a specific finding as to his area of expertise, the undersigned noted that Dr. Adler had clinical experience with immunologic issues and that his admitted minimal experience with CVID would go to the weight of his testimony. Tr. at 83.

In his report, Dr. Adler opined that "the administration of the Varivax vaccine aggravated Jane Doe/17's then unknown and asymptomatic preexisting condition of Common variable Immune deficiency (CVID) resulting in gastritis and colitis of autoimmune etiology. . . . This has resulted in the manifestation of symptoms indicating a chronic autoimmune gastritis and collagenous colitis." P Sub. 5 at 4. Dr. Adler testified consistently with his written opinion. Dr.

¹⁰ "Common Variable Immunodeficiency (CVID) is a disorder characterized by low levels of serum immunoglobulins (antibodies) and an increased susceptibility to infections." P Sub. 4 at 12.

Adler stated that petitioner has a documented hypogammaglobulinemia¹¹, a common form of CVID, based upon her blood serum levels that were frozen both before and after her vaccinations. Tr. at 86. Dr. Adler testified that petitioner's second vaccination triggered "an abnormal immune response due to her low IgG levels and possibly other components that have not been formally detected that resulted in an autoimmune response, which manifested in her situation by a form of hypersensitivity reaction." Tr. at 89.

Dr. Stephen J. McGeady, M.D.

Dr. McGeady is a professor of pediatrics at Thomas Jefferson University. Respondent's Exhibit (R Ex.) B at 1; Tr. at 134. Dr. McGeady is board-certified in pediatrics, and is certified by the American Board of Allergy and Immunology and the sub-board of Diagnostic Laboratory Immunology. Id. Dr. McGeady belongs to various professional memberships, including the American Academy of Allergy Asthma and Immunology, the Clinical Immunology Society and several local organizations. Id. He has published, including a publication on CVID. Tr. at 135; see R Ex. B at 5, article 43. After voir dire the undersigned found Dr. McGeady qualified as an expert in immunology. Tr. at 143.

Dr. McGeady opined that petitioner did not have CVID at the time the varicella vaccinations were administered. Tr. at 147. Dr. McGeady testified that CVID is a condition characterized by a deficiency of IgG and IgA, noting that sometimes all of the immunoglobulins are absent. Tr. at 145. Dr. McGeady further testified that petitioner did not meet the criteria for CVID at the time of her vaccinations as her IgA and IgM levels were normal, and her IgG level was low, though it was not "terribly diminished." Tr. at 148. He elaborated that when making a diagnosis of CVID "a general rule of thumb is that the IgG level, you'd expect it to be below 400, and hers was not." Id.; see P Sub. 8, Ex. 14 at 1 (March 7, 2001 petitioner's IgG level was 597; June 4, 2001 it was 559; September 6, 2001 it was 605.) Dr. McGeady explained that a lower IgG level, but not below 400, could be found on a healthy person, but it could also be found in a person "destined to develop" CVID, but who "has not achieved that level yet." Tr. at 148.

Further, he opined that the cause of collagenous colitis is idiopathic. Tr. at 186. He testified as to being unaware of any known association between CVID and collagenous colitis. Tr. at 160. Dr. McGeady also found it extremely unlikely that Varivax vaccine could precipitate the activation of a dormant CVID. Tr. at 161. When questioned, both Dr. Adler and Dr. McGeady testified that it would be difficult to ascertain whether petitioner's diarrhea that presented at some point after vaccination was the result of her previous IBS or if it was a manifestation of collagenous colitis. Tr. at 105, 157.

B. Legal Standard

¹¹ "Abnormally low levels of all classes of immunoglobulins in the blood." Dorland's Illustrated Medical Dictionary (30th ed. 2003) 894.

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.¹²

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. §14(a). Petitioner does not allege a table injury. Petitioner instead alleges that the varicella vaccine “significantly aggravated a pre-existing condition.” Pet. at 1.

The Vaccine Act defines significant aggravation as:

any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

§33(4). Thus, for petitioner to prevail in her claim, she must prove that her pre-existing condition (the alleged immune deficiency) was significantly aggravated following her varicella vaccinations, and that the significant aggravation of her immune deficiency was caused-in-fact by her vaccination. §11(c)(1)(C)(ii)(I). Testimony from a reliable¹³ medical expert must support

¹² A preponderance of the evidence standard requires a trier of fact to “believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.” In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

¹³ The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication;

petitioner's case. §13(a); see also H.R. Rep. No. 99-908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), reprinted in 1986 U.S. Code Cong. & Admin. News 6344, 6356 ("Evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation."). Jane Doe/17's case is measured against these standards.

C. Analysis

Petitioner has not alleged a table injury in this case; nor has petitioner alleged that the varicella vaccine caused-in-fact her current condition. Pet. at 1. Petitioner alleges, and her expert testified accordingly, that the varicella vaccine significantly aggravated her pre-existing condition of CVID. Id.; see also P Sub. 5 at 5. Thus, the issue to be resolved is whether petitioner has demonstrated by a preponderance of the evidence that the varicella vaccinations she received on March 7, 2001 and June 4, 2001 more likely than not significantly aggravated her alleged pre-existing CVID. For the following reasons the undersigned finds that petitioner failed to prove that she suffered from a pre-existing injury and thus there was no injury that the vaccine could have aggravated. In addition, the undersigned finds that petitioner's case suffers from several additional medical and factual deficiencies, any one of which proves fatal to petitioner's claim.

Since this case presents a number of differences between the experts in this case, it is critical to discuss their relative credibility. In short, Dr. Adler was not credible; Dr. McGeady

whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 594. However, the Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

. . . submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 ("The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

was very persuasive. While the undersigned is certain that Dr. Adler is a fine clinician, he simply comes up short as an expert. In addition to having never published “anything”, tr. at 82, Dr. Adler conceded “minimal” experience with CVID and has never diagnosed it. Id. As will be discussed later, his testimony regarding the criteria for diagnosing CVID runs counter to literature submitted not only by respondent, but by petitioner as well. Compare Tr. at 93 with R Ex. D at 1; R Ex. E at 1; P Sub. 4 at 16. In addition, Dr. Adler’s unduly heavy reliance on petitioner’s statements of family medical history for support of his medical opinion is extremely dubious. While clearly doctors rely on historical information for a piece of the medical puzzle, no credible doctor testifying before the undersigned over the past 20 years has based findings solely upon a petitioner’s statements in the absence of supporting clinical or laboratory data. One example of Dr. Adler’s unjustifiable reliance upon Jane Doe/17’s uncorroborated statements was where he testified that his review of the medical records showed a “significant” family history. Tr. at 84. Dr. Adler continued that these records show that the “[m]other and other first degree relatives, who have had a suggestion of autoimmune type reactions to various events . . .” Id. at 84-85. When asked by the court where in the record these documented events appear, Dr. Adler responded that “I have roughly 600 pages of records of Jane Doe/17’s family history as was given by her. . . .” Id. at 85. When pressed further, Dr. Adler conceded that he never spoke to Jane Doe/17 about her family history and conceded that he had no records of her family history. Id. at 86. This “significant” family history comes from petitioner’s own statements which are undocumented, unsupported and represent her self-diagnosis of her medical issues. See P Sub. 3 at 1-15; see also Tr. at 88-89 (Dr. Adler concluded that Jane Doe/17 had “fairly severe reactions” to her polio and Rabies vaccinations based solely upon her representations.). Dr. Adler’s blind acceptance of this information is simply inappropriate and called into question the remainder of his testimony.

On the other hand, the court found Dr. McGeady to be extremely well-qualified and knowledgeable on the medical issues discussed. The undersigned also was impressed with Dr. McGeady’s preparation - his knowledge of the extensive record - and his testimony consistent with that record. Thus, to the extent that resolution of this case hinged on resolving medical issues, the undersigned relied on information provided by Dr. McGeady to resolve those issues.

Beyond the determination of expert credibility, which in and of itself is sufficient to support a finding against petitioner, this case suffers from numerous medical and factual deficiencies that also support finding against petitioner. The undersigned will not address each and every deficiency. However, the undersigned will focus on two primary issues: first, whether petitioner had an “unknown” pre-existing condition that the vaccine could aggravate, and two, the credibility of petitioner. Finding against petitioner on either of these two issues necessarily results in finding against petitioner since her theory of aggravation hinges on the existence of a pre-existing condition and the credibility of petitioner is critical since Dr. Adler relied on her version of the facts to support his opinion. Unfortunately for petitioner, the undersigned answers each of these issues in the negative.

Dr. Adler’s opinion is that the varicella vaccine “aggravated Jane Doe/17’s then unknown and asymptomatic preexisting condition of Common variable Immune deficiency (CVID)

resulting in gastritis and colitis of autoimmune etiology.” P Sub. 5 at 4. Dr. Adler testified consistent with his written opinion. At the conclusion of his testimony, the undersigned confirmed with Dr. Adler that his opinion hinged on the existence of CVID in Jane Doe/17 prior to her varicella immunizations. Tr. at 131-32. Thus, the critical issue to be decided is whether Jane Doe/17 had CVID prior to her immunizations. Dr. Adler says yes; Dr. McGeady says no.

What is Dr. Adler’s evidence of CVID prior to immunization? Dr. Adler defined petitioner’s condition as “hypogammaglobulinemia”, which is a form of CVID. Tr. at 92. He says that “a deficient IgG level, a history of abnormal immunologic responses and a family history that [Jane Doe/17] presented” is evidence of the pre-existing condition. Tr. at 97. The primary problem with this testimony is that it conflicts with the textbook requirements for diagnosing this disorder. See R Ex. D at 1 (“CVID is diagnosed on the basis of an impaired ability to produce specific antibodies after vaccination or exposure; markedly reduced serum levels of IgG, IgA, and frequently IgM; and exclusion of other causes for antibody deficiency.”); R Ex. E at 1 (“The diagnosis of CVID depends on . . . finding serum IgG and IgA and /or IgM levels that are substantially reduced and finding that antibody responses are deficient.”); see also P Sub. 4 at 12 (The degree of serum immunoglobulins vary in patients, some patients experience “a decrease in both IgG and IgA; in others, all three major types (IgG, IgA and IgM) of immunoglobulins may be decreased.”). When presented with these definitions, Dr. Adler responded that “these are textbook definitions, which in a clinical practice . . . would be nice to have all of these things present . . . [but] it is really not necessary to have every single one of these attributes.” Tr. at 97. Unfortunately for Dr. Adler, the literature submitted by both parties says otherwise, consistently stating that to diagnose CVID requires a “markedly” or “substantially” reduced level in at least the IgG and IgA immunoglobulins. Dr. Adler’s contention that a low level of IgG would support the diagnosis of CVID, tr. at 92, simply conflicts with the literature submitted by both parties. Beyond his unsubstantiated statements, Dr. Adler referenced no support for his contrary view. Based upon the evidence in the record, the undersigned finds Dr. Adler’s stated position not reliable and thus not credible.

The contrast between Dr. Adler’s testimony and that of respondent’s expert, Dr. McGeady, was striking. Dr. McGeady testified that in his experience he has seen approximately 40 patients with CVID. Tr. at 135. Dr. McGeady defined CVID consistently with the submitted medical literature as:

It’s a condition where despite the fact that the immune system appears to have the requisite cells to produce immunoglobulin and make specific antibody that these cells seem unable to do that, and it’s characterized by a deficiency of at least IgG and IgA and sometimes all of the immunoglobulins are absent.

Tr. at 145; see R Ex. D at 1. In diagnosing CVID, Dr. McGeady testified that the first thing one would do is “get a history, which is consistent with CVID.” Tr. at 146. A history would generally be one of recurring infections in the sinuses and respiratory system. Tr. at 146. When questioned about how to test for CVID, Dr. McGeady responded that to test for CVID, “first obtain a study of the immune globulins in the serum” to establish that both IgG and IgA levels

are diminished. Tr. at 147. Next, once diminished levels of immunoglobulins are established test to see whether the patient can make antibody. Id. Then, look to the different type of lymphocytes in the patient's blood to determine if B cells¹⁴ are present. Id. If B cells are completely absent then "that would take the person out of common variable immunodeficiency, and put them in a different category." Id.

Dr. McGeady opined that petitioner did not meet the criteria for CVID at the time of vaccination. Tr. at 148. The reasons he elicited were that petitioner's IgA level was within the normal range, her IgM level was within the normal range and her IgG, though diminished, the values did not fall below 400, which "as a general rule of thumb" would be expected in patients presenting with CVID. Tr. at 148. The values for petitioner's IgG, from previously frozen serum tested on July 20, 2007 were 597 for the serum drawn March 7, 2001, 559 drawn June 4, 2001, and 605 for September 6, 2001. See P Sub. 8, Ex. 17 at 4. The normal range listed by the laboratory that performed the test was a range of 650-2000. P Sub. 8, Ex. 17 at 2. Dr. McGeady testified that an IgG below normal range could be found in a healthy person, a position petitioner's expert Dr. Adler concurred with. Tr. at 148, 101. Dr. McGeady also stated that a below normal range of IgG, but not below the 400 range could be found in a patient who is headed in the direction of developing CVID, "but has not achieved that level yet." Tr. at 148.

Dr. McGeady also pointed out that absent from the record was any evidence indicating petitioner was not able to make antibody at the time of her vaccinations. Tr. at 148. Dr. McGeady emphasized that the inability to produce antibody is a critical issue with CVID. Tr. at 152; see also R Ex. D at 1 (One criteria for diagnosing CVID is the "impaired ability to produce specific antibodies after vaccination or exposure."); P Sub. 4 at 16. Contrary to Dr. Adler's testimony that "these folks may go a lifetime without having any symptoms", tr. at 87, Dr. McGeady responded that based upon his experience and the literature he did not agree. Tr. at 151. He stated that CVID is "not a subtle disease." Tr. at 149. He explained that in his view it was not a disease that "creeps up on you", and "[i]f you have it, I think you know there's something wrong." Tr. at 150. He explained that a frequent scenario with someone with CVID would be the body unable to fight infection resulting in a person becoming frequently ill, mostly via infections in the sinuses and lungs. Tr. at 150-51. He stated that he would expect Jane Doe/17 to have many symptoms, even more so due to her exposure to people with infectious disease through her work as a nurse at a hospital. Tr. at 149. In response to the undersigned's question about why someone with an immunodeficiency would be frequently ill, Dr. McGeady stated that the body is unable to fight off infections because it is unable to produce antibodies. Id. at 151-52. The undersigned notes the lack of documentation that shows any repeated and/or frequent pulmonary infections that one would expect to see if Jane Doe/17 did suffer from CVID prior to vaccination. In fact, petitioner testified that at the time of the vaccinations, she "was very healthy" so she "barely" saw the doctor. Tr. at 59. Considering Jane Doe/17's consistent exposure to infectious disease in the hospital work-place, the absence of infection is glaring.

The undersigned finds Dr. McGeady's testimony concerning CVID far more convincing

¹⁴ B cells are "[t]he cells that are precursors of the antibody forming cells." Tr. at 147.

than Dr. Adler's. Dr. McGeady's experience as an immunologist, his experience with patients diagnosed with CVID, and the consonance between his testimony and the submitted medical literature combined to make him the vastly more persuasive. In contrast, Dr. Adler had neither factual nor medical support for his opinion and was quite unimpressive as an expert. Thus, based upon the information discussed above, the undersigned finds that petitioner has not proven by the preponderance of the evidence that she had an immune deficiency at the time of her varicella vaccinations. Accordingly, in accordance with petitioner's theory of her case, the vaccine could not have aggravated a pre-existing condition, because there is no persuasive evidence of an underlying condition.

There are significant factual holes in petitioner's case as well. A further deficiency in Dr. Adler's opinion was the great weight he put on petitioner's "significant" family history for a suggestion of autoimmune type reactions to various events. Tr. at 84. The undersigned clarified that Dr. Adler did not review any medical records of petitioner's family, only medical records of petitioner herself.

THE COURT: What information do you have specifically about Jane Doe/17's family other than herself?

DR. ADLER: None

THE COURT: Okay. So when you said you're referring to records of her family history, you have no records of her family history?

DR. ADLER: That's correct.

Tr. at 86. In formulating his opinion that petitioner suffered from CVID, Dr. Adler stated that "a very important piece" of evidence is Jane Doe/17's family history suggesting autoimmune tendencies. Tr. at 131. However, as Dr. Adler conceded, there are no records of any family histories of autoimmune issues. Id. at 86. Petitioner herself alleges that her "family has a high incidence of severe reactions to immunizations." P Sub. 3 at 5. The bases for that statement are an alleged anaphylactic reaction by her daughter to a smallpox vaccination and an alleged anaphylactic reaction by her father to a tetanus immunization. Id. No documentation of either was submitted. There is no way to know if either of these events occurred and whether the two events constitute a familial history of autoimmune issues. Dr. Adler simply assumed in his testimony that the answer was "yes." No explanation was offered. In addition, Dr. Adler did agree that genetics does not always play a role in CVID. Tr. at 101. In fact, literature submitted indicates that only about 10% of the cases are familial. R Ex. D at 1. In the final analysis, Dr. Adler had no basis for relying upon petitioner's own statements to conclude that there exists a familial autoimmune issue.

There is a similar problem with Jane Doe/17's, in Dr. Adler's words, "documented records of abnormal immunologic responses to immunizations" in childhood. Tr. at 87. There is no documentation of any reactions. There are histories given by Jane Doe/17. Dr. Adler relied upon her affidavit, not "documented records", for his opinion. Id. at 85. In her affidavit, Jane Doe/17 relates that following receipt of her oral polio vaccine in 1960, she suffered pneumonia for two weeks. P Sub. 3 at 4. Following receipt of the oral polio vaccine in 1962, she again

suffered pneumonia. Id. at 4-5. Petitioner submitted report cards showing absences from school as support for her contention. Id. at 16-19. Petitioner also relates receiving a Rabies vaccine and suffering serum sickness subsequently. Id. at 7. It simply is incredible that Dr. Adler would rely on these histories, dating back nearly 50 years ago, for support of a pre-existing immunologic disorder. First is the obvious memory issue. Did Dr. Adler even consider that Jane Doe/17 is mistaken in her memory of events so far in the past? There is no indication that Dr. Adler made any effort to verify Jane Doe/17's statements regarding these medical issues. In fact, he testified that he did not speak to Jane Doe/17. Tr. at 86. Jane Doe/17 referenced to school report cards to "verif[y]" the absences. P Sub. 3 at 4. Dr. Adler stated that he did review those report cards and drew "an inference" from that information. Tr. at 100. A review of the report cards show that, at best, petitioner missed school during the fall semester of the years she allegedly received the polio vaccines. See P Sub. 3 at 16-19. There is no way to tell when during the fall petitioner was absent, why she was absent and if it was for individual illnesses or for one extended absence. Interestingly, for the years not in question, the absences were cut off in the copying so that one cannot tell what petitioner's attendance record was for those periods. In any event, the report cards add no support to petitioner's contention that she suffered pneumonia following her receipt of the oral polio vaccines. Also, there is no evidence supporting a causal link between any oral polio vaccines and the alleged, but not proven, episodes of pneumonia. Dr. Adler made no effort to explain how the oral polio vaccine would cause pneumonia, and the undersigned, who happened to handle all of the oral polio litigation under the Vaccine Act, never heard of such an association. Thus, Dr. Adler's reliance on Jane Doe/17's alleged past vaccine reactions as proof of her "abnormal immunologic response", tr. at 87, is unfounded.

A similar evidentiary problem exists with regard to petitioner's statement that she experienced the "sudden onset [of] life threatening serum sickness" following a Rabies vaccine. P Sub. 3 at 7. Again, there is no medical documentation of the immunization or any hospitalization. Secondly, as will be discussed infra, petitioner has numerous credibility issues that rendered her testimony unreliable. Thus, there is not a factual basis for Dr. Adler to rely upon this "serum sickness" reaction to the Rabies vaccine.¹⁵

For all of the above reasons, petitioner failed to show by a preponderance of the evidence that she suffered from a pre-existing CVID. Since petitioner's claim, and Dr. Adler's medical theory, is that the immunizations aggravated a pre-existing CVID, the failure to prove the pre-existing CVID necessarily means that there could be no aggravation. Accordingly, petitioner failed to prove her case. However, the undersigned will discuss petitioner's credibility, since it was so important to this case.

¹⁵ There is a dispute as to whether serum sickness is an autoimmune disease. Dr. Adler relied upon this serum sickness as evidence of an "abnormal immunologic response" to petitioner's prior immunizations. P Sub. 3 at 87. However, Dr. McGeady testified that serum sickness is not an autoimmune disease whereby "your immune system is attacking your own tissues," but exist when the immune system combines with exogenous material and "[y]our own tissues are innocent bystanders of an inflammatory reaction." Tr. at 153. Ultimately, it is not necessary to resolve this issue.

Petitioner's credibility is a key component of this case because much, if not all, of the information Dr. Adler relied on for formulating his opinion is not documented in the contemporaneous medical records, but is attributable to petitioner. It is boilerplate law that petitioner's expert's opinion is only as good as its factual predicate. Castillo v. HHS, 1999 WL 605690 at *13 (Fed. Cl. Spec. Mstr. July 19, 1999) (citing Davis v. HHS, 20 Cl. Ct. 168, 173 (1990)); Loesch v. United States, 645 F.2d 905, 915 (Ct. Cl. 1981) (citing State of Washington v. United States, 214 F.2d 33, 43 (9th Cir. 1954), cert denied, 348 U.S. 862 (1954)). In this case, the undersigned finds petitioner's testimony not credible. Accordingly, Dr. Adler's opinion fails for the additional reason that it has no factual predicate.

There are two primary reasons for finding Jane Doe/17's testimony not credible: (1) her testimony regarding her IBS is either evidence of such an extremely poor memory that nothing she said can be taken as accurate or, quite simply, she lied; and, (2) her testimony conflicts with information contained in the contemporaneous medical records.

The issue of petitioner's IBS is very important to unraveling petitioner's medical issues. Both Dr. Adler and Dr. McGeady testified that they would be unable to tell if petitioner's diarrhea occurring post-vaccination was the result of IBS or collagenous colitis. Tr. at 108, 157. Petitioner is claiming that her collagenous colitis is the residua of her vaccine aggravated CVID. Petitioner makes no similar claim for any IBS. Thus, if petitioner was suffering from continuing IBS, that began prior to her immunizations, her expert presumably would not be able to opine to a cause. Based on information filed after the Hearing, it appears without any doubt that, contrary to Jane Doe/17's contentions, petitioner's IBS was an ongoing problem prior to vaccination.

Petitioner's medical records show she suffered from IBS, beginning at age 24. Dr. Fishman's letter notes that petitioner suffered her first symptoms of IBS at age 24 and over a couple years her symptoms improved until they reached her "baseline which has been more intermittent and mild." P Sub. 2 at 84. The record continues by noting that over the past eight months her symptoms "have been worsening again." Id. During her testimony petitioner was questioned regarding whether she had any history of bowel problems prior to vaccination. Petitioner was asked whether she had any remarkable problems with her bowel movements prior to entering the study. Tr. at 43. She responded "I mean, not that I noticed...I mean if they were a little loose, I wouldn't have noticed until it became a problem." Id. She was later questioned during cross-examination again regarding any previous bowel problems:

RESPONDENT'S COUNSEL: Your history of irritable bowel syndrome is referenced in several places including on the VAERS report as a preexisting condition. I want to make sure I understand your testimony. When you were 24, you were pregnant, and you had a case of irritable bowel syndrome. Is that your testimony?

PETITIONER: Yes, mam'm. Yes, mam'm. I had four pregnancies in five and a half years, and actually yes, I delivered my forth son a month early. I developed some severe diarrhea, and they did not do a colonoscopy. I don't even know if they did them back then. They did a barium enema. They called it irritable bowel syndrome because they

didn't know what it was.

In retrospect now, my GI doctor is telling me that pregnant women, the babies suck the IgG out of them. If I was hypogammaglobulinemic, this may have been another whatever. **I've had no problems since a year after my son was born.**

Tr. at 62 (emphasis added). The undersigned also questioned petitioner on this issue:

THE COURT: The question goes to the history, mam'm. You said you had one bout of irritable bowel at the time of your pregnancy, and that was it?

PETITIONER: Right.

Tr. at 63; see also Pet. at 2. The undersigned questioned petitioner further about the apparent conflict in petitioner's testimony and Dr. Fishman's consult letter which gives the impression that petitioner was still experiencing some milder and more intermittent continuing problems with her bowels. Tr. at 63. Petitioner's explanation is that Dr. Fishman "misunderstood" her bowel complaints and that her constipation and diarrhea were linked to her menstrual period. Id.

This issue remained somewhat ambiguous until following the Hearing petitioner filed records from her disability claim. Unfortunately for petitioner, her testimony conflicts directly with records provided by the Social Security Administration (SSA). According to the SSA records, petitioner filed a claim for disability in 2000 detailing her complaints; alleging severe mental depression, anxiety, post-traumatic stress, and **"chronic, uncontrolled diarrhea from spastic colon."** P Sub. 11 at 463 (emphasis added). This claim was filed less than a year prior to vaccination. Id. Petitioner, in her application for disability, reported her symptoms became problematic on March 15, 1995, and that she was unable to work due to her condition on May 30, 2000. Id. Additionally, she related to a medical professional in April 2000 that she suffered from "what is called an atonic colon." Id. at 450. In petitioner's Post-Hearing Brief petitioner attributes the diarrhea referenced in the SSA application to two medications she was taking, Celexa and Klonopin. P Post-Hearing Brief, filed February 29, 2008, at 2. That explanation rings hollow. A "chronic" condition is by definition a prolonged or long lasting condition and is not consonant with a side affect from a medication. Neither is an "atonic colon." Atonic is defined as lacking normal muscle tone. See n. 6, supra. Both the atonic colon and spastic colon indicate that petitioner was experiencing bowel issues for a period far exceeding the single incident she testified occurred 30 years ago when she was 24. See Tr. at 62. The pre-existing bowel issues are supported by another record - the log from the clinical trial. On August 8, 2003, Dr. Brady created an Adverse Event for Jane Doe/17. P Sub. 2 at 4. The description of the event includes the diagnosis of collagenous colitis in March of 2002 and the symptoms of diarrhea. Id. Most interesting is the statement that "[h]as a pre-existing condition of irritable bowel syndrome." Id. This statement had to come from petitioner herself. Thus, petitioner's testimony that prior to vaccination she did not suffer from bowel problems other than a bout of IBS at age 24 is directly contradicted by Dr. Fishman's history taken in 2002, the history recorded in the research log taken in 2003, and the information petitioner gave to SSA in 2000.

Unfortunately, petitioner's "selective" memory or dismissive explanations were evident several other key times throughout the proceedings. For example, when asked about Dr. Fishman's letter which confirms petitioner's bowel problems at age 24, but indicates that the problems have continued, petitioner responded "[h]e misunderstood that." Tr. at 39. We now know through the SSA documents that Dr. Fishman's history, not petitioner's explanation, was correct. During another exchange on cross-examination, Jane Doe/17 was asked about her primary physician, Dr. Corey. Jane Doe/17 offered that she was very healthy and had not seen Dr. Corey in "maybe" two years. However, when shown Dr. Corey's records, P Sub. 2 at 160, petitioner conceded that she was seeing Dr. Corey for stress and was taking antidepressants. Tr. at 59-60. More importantly for purposes of Jane Doe/17's credibility, this record from June 5, 2001 states that Jane Doe/17 has been "seen regularly" over the past six years for stress related medications. In the face of this record, Jane Doe/17's testimony that she could not recall the last time she saw Dr. Corey and that it was "maybe two years", if an isolated error would be seen as a minor memory lapse, but in conjunction with other testimonial lapses is seen as a pattern of covering up potentially damaging information. One last similar example was when Jane Doe/17 replied that she could not recall seeing any doctors, other than Dr. Corey, in the summer of 2001. However, once again, when shown the medical records Jane Doe/17 had to concede that she saw a chiropractor six times that summer and a dermatologist, Dr. Weiss, for a "full skin exam." Tr. at 70-71. Of note, Dr. Weiss's physical examination done on August 2, 2001, indicates a "healthy, well-appearing woman." P Sub. 2 at 246. When asked whether she told Dr. Weiss of her bowel problems, Jane Doe/17 replied that she did not recall. Tr. at 71.

Lastly, it must be noted that the only contemporaneous record that provides support for the alleged onset of petitioner's bowel issues shortly after her second immunization is Dr. Fishman's March 11, 2002 letter. P Sub. 2 at 84. This letter both hurts petitioner's case and provides some support. As discussed above, it hurts her case because it indicates that her bowel problems continued past that isolated event at age 24. Jane Doe/17 said this portion of the letter is incorrect as Dr. Fishman "misunderstood." However, the letter provides support for Jane Doe/17's timing allegation in that it states "over the past eight months her symptoms have been worsening again." Id. Interpreted literally, that would mean that the symptoms began worsening from about July 2001, which is one month following her second immunization. The problem for petitioner is that Dr. Fishman had the symptoms worsening from a pre-existing bowel problem, not from the immunization as alleged by petitioner. And that is the problem petitioner faces throughout this entire record. Despite repeated opportunities, the records do not reflect the occurrence of problems alleged by petitioner in the time frame alleged by petitioner. Petitioner stated that she told Dr. Kathleen Brady of her bowel issues following vaccination. Tr. at 23. Petitioner had "face-to-face" meetings where she reported the diarrhea. Id. at 66. These meetings produced information that was kept in a log of the study. Id. Petitioner testified that Dr. Brady did not think the bowel issues were related to the immunizations. Id. The "Comments" section of the log does not support petitioner's version of the events. See P Sub. 2 at 12-16. The "Comments" section of the log of the study indicates that petitioner's chief complaint in the months following vaccination was on July 16, 2001, where petitioner reported tenderness, redness and induration of her left deltoid. Id. at 8, 14. It also states that "No other symptoms reported." Id. The records from the study do not indicate bowel problems being

reported until March 20, 2003. Id. at 11. Petitioner's self-report, dated June 2003, states that "Retrospectively (06/03) reported loose stools beginning ~ 7/4/01." Id. at 8. Otherwise, there appears to be no significant complaints in the records of the study organizers. See Id. at 12-13 (Petitioner denies adverse events on September 6, 2001. Petitioner has "no complaints" on March 5, 2002.).

Petitioner attempts to explain the lack of documented complaints in petitioner's Post-Hearing Responsive Brief (hereinafter P Responsive Brief) filed on April 18, 2008. Petitioner asserts that there is a valid reason for her complaints not being reported. P Responsive Brief at 1. Petitioner contends that she stopped reporting information about her complaints because Dr. Brady told petitioner that per petitioner's testimony she "had no knowledge of diarrhea having anything to do with varicella vaccine." Id. at 1; Tr. at 23.

The undersigned is not convinced by petitioner's argument in her Responsive Brief as to why there is no documentation of loose stools in the contemporaneous medical records. Petitioner testified to reporting her symptoms to Dr. Brady, yet there is no record of her complaints. At the undersigned's suggestion, after the Hearing the parties contacted Dr. Brady to ascertain if she was able to provide any additional insight into this matter. A review of notes taken by the undersigned's office during a status conference conducted on January 3, 2008, indicates that the parties informed the undersigned that Dr. Brady had no recollection or records documenting Jane Doe/17's alleged reaction to the vaccine. Office notes from status conference, dated January 3, 2008. Both parties agreed that Dr. Brady was not able to provide any additional information regarding Jane Doe/17's complaints. Id. Petitioner's counsel stated that Dr. Brady was saying she did not hear of anything until eight months later. Respondent also added that Dr. Brady stated anything she was told would be in the records. Id. Based upon the information in the medical records and petitioner's highly questionable testimony, the undersigned is not persuaded by petitioner's testimony that she reported her complaints as early as two weeks post-vaccination.

In conclusion, petitioner's case fails because a preponderance of the evidence does not support the existence of a pre-existing immunologic disorder, CVID, prior to her immunizations. Thus, petitioner's medical theory must fail since the vaccines could not have aggravated that which was not proven to exist. In addition there was no factual predicate for petitioner's expert's opinion as the undersigned found petitioner not to be credible. Accordingly, the undersigned finds that petitioner has not established by a preponderance of the evidence that the varicella vaccinations petitioner received on March 7, 2001 and June 4, 2001, more likely than not significantly aggravated a pre-existing condition.

Petitioner's claim is denied. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master